HEMPE, Barbara [DE/DE]; Rosenstr. 23, 24576 Bad Bramstedt (DE). WALTHER, Christoph [DE/DE]; Dorf-strasse 35, 24568 Kattendorf (DE).

(74) Agents: BOTH, Georg et al.; Uexküll & Stolberg, Besel-erstrasse 4, 22607 Hamburg (DE).

(54) Title: FLEXIBLE IMPLANT

(57) Abstract: A flexible implant has a mesh-like basic structure of monofilaments, the diameter of which lies in the range from 0.02 mm to 0.30 mm and the bending elasticity modulus of which is smaller than 3500 N/mm². The basic structure contains pores the size of which lies in the range from 1.5 mm to 8.0 mm over more than 90% of the total area of the pores. The bending force of the basic structure, measured in a three-point bending test with a span of 11 mm and normalized to a sample width of 10 mm, is 30 mN at most.

Flexible Implant

The invention relates to a flexible implant with a mesh-like basic structure.

Flexible implants with a mesh-like basic structure are widespread, e.g., in the form of implant meshes. They are inserted into the patient's body during a surgical procedure, e.g. at the abdominal wall, in order to reinforce the body tissue at least temporarily and to prevent complications such as e.g. hernias.

Such implant meshes are frequently produced from mono-filaments, e.g., from polyethylene and in particular from polypropylene. US 3 124 136 A shows an implant mesh of polyethylene with a pore size of less than 1 mm. In US 4 452 245 A a double-laid implant of polypropylene mono-filaments is described in which the pores of the mesh structure are greater than 1 mm.

As a rule, commercial implant meshes of monofilaments have small pores and are relatively rigid. This causes a permanent mechanical stimulus and an irritation of the tissue at the site of the surgery and often leads to the formation of cicatricial layers.

There are also commercial implant meshes of multifilament yarns, e.g. polyester or polypropylene. Resorbable materials can be used here. Thus, e.g., partly resorbable meshes are known in which, apart from polypropylene,

polyglactin 910, a copolymerisate of 9 parts glycolide and 1 part lactide, is used.

Although implant meshes of multifilament yarns are relatively soft, the multifilament yarns have a large surface and show a capillary effect, which can lead to undesired tissue reactions and is associated with a danger of infection for the patient.

The object of the invention is to provide a flexible implant which is tissue-friendly and relatively soft and behaves largely inertly.

This object is achieved by a flexible implant with the features of claim 1. Advantageous designs of the invention result from the dependent claims.

The flexible implant according to the invention contains a mesh-like basic structure of monofilaments, the diameter of which is in the range from 0.02 mm to 0.30 mm (preferably in the range from 0.05 mm to 0.30 mm) and the bending elasticity modulus of which is smaller than 3500 N/mm^2. The basic structure contains pores the size of which lies in the range from 1.5 mm to 8.0 mm over more than 90% of the total area of the pores. The bending force of the basic structure, measured in a three-point bending test with a span of 11 mm and normalized to a sample width of 10 mm, is at most 30 mN.

The mesh-like basic structure is preferably the only component of the implant according to the invention. Additional components can also be provided, however, e.g. a coating of the basic structure or additional threads in-

serted into the basic structure with other properties than the monofilaments of the basic structure have.

The mesh-like basic structure of the implant according to the invention consists of monofilaments. Thus the surface which can come into contact with the tissue or the tissue liquids is relatively small. There is no capillary effect and the danger of infection is minimal. The monofilaments, which as a rule have a smooth surface, behave essentially inertly. The implant according to the invention thus has the good properties of implant meshes which are produced from monofilaments.

Surprisingly it turned out that given the choice of parameters mentioned above for the monofilaments and the basic structure, despite the use of monofilaments, a soft implant can be made which causes, at most, slight mechanical irritation of the tissue (e.g. of the peritoneum) and causes no, or only slight, adhesions. The implant according to the invention thus also has the advantages of the implant meshes of multifilaments.

The bending elasticity modulus of the monofilaments is a material property which corresponds to the Young's modulus (measured in a bending test). With the plastics used for monofilaments, the bending elasticity modulus depends inter alia somewhat on the production conditions (in particular the stretching conditions and the thermal post-treatments) and dimensions of the monofilaments. The value of 3500 N/mm^2 is lower than the bending elasticity modulus of usual polypropylene monofilaments for mesh production, which is of the order of 5000 to 9000 N/mm^2. The monofilaments of the mesh-like basic structure are

thus relatively soft and have a high flexibility with a diameter in the range from 0.02 mm to 0.30 mm.

The predominant share of the pores (i.e. the proportion of the pores which accounts for more than 90% of the total area of the pores in the basic structure) has a size in the range from 1.5 mm to 8.0 mm, and is therefore relatively large. This contributes to a minimisation of the mechanical tissue irritation originating in the implant. Individual pores of the basic structure may (e.g. for production reasons) be smaller than 1.5 mm, but this has no noteworthy effect on the overall properties of the implant.

The flexibility or softness of the implant depends not only on the monofilaments used as material and the size of the pores as such, but e.g. also on the weft-knitted or warp-knitted structure of the basic structure and the matching of the parameters to each other. Thus an upper limit for the bending force of the basic structure is stated as a further parameter which characterizes the implant according to the invention. This bending force emerges from the evaluation of a force-path diagram in which the deflection (i.e. the path) of a sample of the basic structure is plotted as a function of the force acting on the sample. For this, a sample of the basic structure is placed on two supports, 11 mm apart, the force acting perpendicular to the sample and in the middle between the two supports. The deflection increases as the force grows, until the force reaches a maximum and falls again as the deflection continues to increase. This maximum force is called bending force and is normalized to a sample width of 10 mm. The bending force is there-

fore a measure of the elasticity behaviour of the implant as a whole.

Suitable as materials for the monofilaments of the basic structure are, e.g., thermoplastically workable fluorinated homopolymers, thermoplastically workable fluorinated copolymers, polyolefins and mixtures of such materials.

The basic structure preferably contains monofilaments of polyvinylidene fluoride, copolymers of vinylidene fluoride and hexafluoropropene and/or mixtures of such materials. Mixtures of polyvinylidene fluoride (PVDF; thus a homopolymer of vinylidene fluoride) and a copolymer of 95 wt.-% vinylidene fluoride and 5 wt.-% hexafluoropropene are particularly suitable. The mixture ratio of the homopolymer to the copolymer can be, e.g., 50 : 50 or 80 : 20; the weight ratio is stated each time. Such polymers can be coloured in the melt, e.g. with the blue colour pigment copper phthalocyanine blue ("Color Index" CI. No. 74160). Monofilaments with a bending elasticity modulus of approx. 1200 N/mm^2 to approx. 2400 N/mm^2 can be produced from such mixtures.

If polyolefins are used as monofilaments, polyethylene or polypropylene for example are suitable according to selected production conditions.

The basic structure can also contain monofilaments of a resorbable material, e.g. of poly-p-dioxanone or of a copolymer of glycolides and caprolactones. Such a copolymer is marketed for example by Ethicon under the name "Monocryl". If resorbable monofilaments are used, the basic

structure can be made completely, but also only partly, from resorbable material.

Preferably, the tensile strength of at least a part of the monofilaments is at least 400 N/mm². Such tensile strengths can be achieved, e.g., with the above-mentioned mixtures of polyvinylidene fluoride and a copolymer of vinylidene fluoride and hexafluoropropene.

The basic structure preferably contains a weft-knitted product or warp-knitted product, warp-knitted products preferably being made as crochet galloon ware. Weft-knitted products and warp-knitted products have proved suitable for flexible implants and can be made in a plurality of patterns.

In the following the invention is explained in detail by means of embodiments. The drawings show in

Figure 1   the typical shape of a force-path diagram which is measured in a three-point bending test on a monofilament or on the basic structure of a flexible implant,

Figure 2   a schematic illustration of the warp-knitted structure in the case of the implant according to the invention according to example 1,

Figure 3   a schematic illustration of the warp-knitted structure in the case of the implant according to the invention according to examples 2 and 3 and

Figure 4   a schematic illustration of the warp-knitted
            structure in the case of the implant according
            to the invention according to examples 4 and 5.

The shape of a typical force-path diagram is shown in
Figure 1 as results when carrying out a three-point bend-
ing test on a monofilament or on the mesh-like basic
structure of a flexible implant.

The properties listed below of monofilaments can be es-
tablished in such a three-point bending test. A force is
exerted on a monofilament supported at two points in the
middle between the two support points and perpendicular
to the line connecting of the support points. This force
and the deflection of the monofilament ("path") caused by
it are measured. As long as the deflection is small, the
force grows linearly with the deflection, but more slowly
thereafter. After a maximum force is reached, the force
drops while the deflection continues to increase.

The force maximum in the force-path diagram of a given
sample is called the bending force of the sample. The
bending force is a measure of the flexibility behaviour
of the sample, thus the monofilament here. The greater
the bending force, the more rigid the monofilament. The
bending force is given in N and depends on the test con-
ditions, essentially on the distance between the two sup-
port points (span). In the three-point bending tests
which led to the numerical values given below for the
monofilaments, the span was 4 mm. The test speed, i.e.
the speed at which the deflection of the sample is in-
creased, was 50 mm/minute.

. The bending rigidity of the sample can also be measured from the force-path diagram. The bending rigidity is the slope in the linear range of the measurement curve. The unit of measurement is N/mm.

The bending elasticity modulus of a monofilament can be calculated from a force-path diagram, taking the diameter of the monofilament into account. The bending elasticity modulus corresponds to the Young's modulus and is given in N/mm^2. This variable is largely independent of the test conditions, but depends not only on the material as such (like, e.g., in the case of metals), but also somewhat on the production conditions and the dimensions of the mono-filaments.

A three-point bending test can be carried out in an analogous manner on an areal flexible implant or on its mesh-like basic structure. The sample is supported along two lines which run parallel to each other the distance of the span apart.

For the tests in which the parameters stated below of the mesh-like basic structure were established according to the embodiments, the span was 11 mm and the test speed (as for the monofilaments) was 50 mm/minute. In order to minimise edge effects, samples with a width of at least 25 mm were used.

As with the three-point bending tests on monofilaments, the bending rigidity (in N/mm) of the mesh-like basic structure results from the force-path diagram as the slope in the linear range of the curve. In order to be able to compare samples of different widths, a normalisa-tion to the width of the sample took place. The numerical

values given below relate to a sample width of 10 mm. If for example the sample width was actually 25 mm, this standardization took place by dividing the slope read off directly from the force-path diagram by 2.5.

The bending force is obtained by evaluation of the force-path diagram as force maximum of the curve. The numerical values given below were standardized to a sample width of 10 mm. The bending force is a measure of the rigidity of the implant or of the mesh-like basic structure as a whole. The greater the bending force, the more rigid and less flexible the implant.

Again, the bending elasticity modulus can be calculated.

Tables 1, 2 and 3 show respectively, for monofilaments of various materials and with various diameters, the bending elasticity modulus, the bending rigidity and the bending force. These variables were each established using three-point bending tests, as explained.

"PDS" is an abbreviation for poly-p-dioxanone, a resorbable material.

"Monocryl" is an Ethicon trade name for a resorbable co-polymer of glycolides and caprolactones.

"Pronova" is an Ethicon trade name for monofilaments of a mixture of polyvinylidene fluoride (PVDF) and a copolymer of 95 wt.-% vinylidene fluoride and 5 wt.-% hexafluoro-propene. Polyvinylidene fluoride and the copolymer are marketed for example by Solvay Advanced Polymers under the trade name "Solef 1008" and "Solef 11010", respectively. Surgical filaments of such materials are de-

scribed in US 4 564 013 A. In the case of the monofila-
ments of "Pronova" listed in Tables 1 to 3, the mixture
ratio of the homopolymer to the copolymer is 50 : 50 (in
wt.-%).

Table 1

Bending elasticity modulus of various monofilaments

Diameter	Bending elasticity modulus			
[mm]	$[N/mm^2]$			
	PP	PDS	Monocryl	Pronova
0.126	6691			
0.086	8905			
0.18	5097			
0.23	4970			
0.224		1260		
0.173		1575		
0.106		1201		
0.232			537	
0.16			971	
0.132			783	
0.248				1944
0.199				2256
0.136				2118
0.093				1232

Table 2

Bending rigidity of various monofilaments

Diameter	Bending rigidity			
[mm]	[N/mm]			
	PP	PDS	Monocryl	Pronova
0.126	0.065			
0.086	0.024			
0.18	0.197			
0.23	0.152			
0.224		0.1213		
0.173		0.0473		
0.106		0.0057		
0.232			0.0573	
0.16			0.0233	
0.132			0.0087	
0.248				0.274
0.199				0.1247
0.136				0.027
0.093				0.0037

Table 3

Bending force of various monofilaments

Diameter	Bending force			
[mm]	[mN]			
	PP	PDS	Monocryl	Pronova
0.126	23			
0.086	10			
0.18	66			
0.23	157			
0.224		71		
0.173		30.5		
0.106		5.9		
0.232			36.1	
0.16			14.1	
0.132			6.21	
0.248				116.7
0.199				57.7
0.136				14.3
0.093				4.31

Table 4

Properties of the implants according to Examples 1 to 5
and of two conventional implants of polypropylene (PP)

Implant	Pore size	Bending force	Bending rigidity	Bending elasticity modulus
		[mN]	[N/mm]	[N/mm^2]
Example 1	ca. 6.5	2.2	0.00054	0.83
Example 2	ca. 3.5	4.4	0.00141	2.13
Example 3	ca. 5	4.5	0.00165	0.7
Example 4	ca. 2	5.2	0.00082	0.65
Example 5	ca. 3	5.3	0.00213	0.98
PP ("Marlex")	ca. 0.8	116	0.01026	1.57
PP ("Atrium")	ca. 1	33	0.00332	2.2

The monofilaments of PDS, "Monocryl" and "Pronova" are suitable for building up the mesh-like basic structure of an implant according to the invention. For comparison, the numerical values for monofilaments of various thicknesses of polypropylene (PP) are given in Tables 1 to 3. The bending elasticity modulus of polypropylene is greater than 4000 N/mm^2.

While the properties of the monofilaments are largely determined by the diameter and the bending elasticity modulus, thus by the numerical values in Table 1, Tables 2 and 3 illustrate the bending rigidity and the bending force which result directly from the force-path diagrams established in the three-point bending test. For monofilaments which are suitable for the flexible implant according to the invention, the bending rigidity should

preferably be approx 0.08 N/mm at most for a diameter of
0.15 mm and approx 0.5 N/mm at most for a diameter of
0.25 mm. The bending force should preferably be smaller
than approx 30 mN for a diameter of 0.15 mm and smaller
than approx 150 mN for a diameter of 0.25 mm.

Some examples follow of mesh-like basic structures of
which versions of the implant according to the invention
consist. In all cases the basic structures are made as
crochet galloon ware from "Pronova" monofilaments.

Example 1

A monofilament of "Pronova" (see above), with a mixture
ratio of the homopolymer to the copolymer of 80/20 (in
wt.-%) and with a diameter of 0.079 mm, was worked into
crochet galloon ware on a "Raschelina RD3MT3/420SN" type
crochet galloon machine. The production specification as
well as the pattern template emerge from Figure 2 in a
way familiar to the person skilled in the art.

After being warp-knitted, the mesh-like basic structure
was washed and subsequently stretched on a frame and
thermofixed at temperatures between 80°C and 130°C. Af-
terwards the mesh-like basic structure was cut to size as
a flexible implant, packed and subjected to a gas ster-
ilisation with ethylene oxide.

Example 2

Crochet galloon ware was made from a "Pronova" monofila-
ment (see above) of 0.079 mm diameter with a mixture ra-
tio of homopolymer to copolymer of 80/20 (in wt.-%) simi-
larly to Example 1. The production specification as well
as the pattern template emerge from Figure 3.

Subsequently the mesh-like basic structure was washed as in Example 1, thermofixed, packed as a flexible implant and sterilized.

An implant produced in this way was inserted intraperitoneally in the abdominal wall of a rabbit and secured with clips (so-called IPOM-technique, "Intraperitoneal Onlay Mesh"). For comparison, a commercial implant mesh of polypropylene ("Marlex", see below) was implanted in an analogous way. Directly after the surgery the implant according to Example 2 lay flat, and the edges had not rolled up. On the other hand, the implant of polypropylene was lying incorrectly, the edges having slightly rolled up and sticking out from the bottom layer.

Seven days later, the conventional implant mesh had caused very marked adhesions over the whole surface, which was attributable inter alia to a mechanical irritation of the peritoneum. On the other hand, the implant according to the invention was covered by a thin, transparent, smooth mesothelium cell layer. Surprisingly, there were no adhesions.

Example 3

A mesh-like basic structure was warp-knitted as crochet galloon ware as in Example 2 and further processed, the only difference being that in this case a "Pronova" monofilament (see above) with a diameter of 0.093 mm and a mixture ratio of homopolymer to copolymer of 50/50 (in wt.-%) was used. The production specification and the pattern template again result from Figure 3.

Example 4

Crochet galloon ware was produced in a similar way to Ex-
ample 1 from a "Pronova" monofilament (see above) of
0.079 mm diameter with a mixture ratio of homopolymer to
copolymer of 80/20 (in wt.-%). The production specifica-
tion as well as the pattern template result from Figure
4.

Subsequently, the mesh-like basic structure was washed as
in Example 1, thermofixed, packed as a flexible implant
and sterilized.

Example 5

A mesh-like basic structure was warp-knitted as crochet
galloon ware as in Example 4 and further processed, the
only difference being that in this case "Pronova" mono-
filament (see above) with a diameter of 0.093 mm and a
mixture ratio of homopolymer to copolymer of 50/50 (in
wt.-%) was used. The production specification and the
pattern template again result from Figure 4.

The approximate pore size, the bending force, the bending
rigidity as well as the bending elasticity modulus are
compiled in Table 4 for the five implants according to
the invention according to Examples 1 to 5 as well as for
two conventional implants of polypropylene ("Marlex" and
"Atrium"). "Marlex" is a trade name for implant meshes
marketed by C.R. Bard Inc.; "Atrium" is the name given to
implant meshes marketed by Atrium· Medical Corporation.

The pore size is the greatest pore width of the mesh-like
basic structure and was determined with a measuring mag-
nifier.

The bending force and the bending rigidity were measured using three-point bending tests, as explained above. These variables were normalized to a sample width of 10 mm. The bending elasticity modulus is calculated from the shape of the curve, taking into account the thickness and width of the sample.

It will be seen that the bending force and the bending rigidity correlating with the bending force are clearly lower in the case of the versions of the implant according to the invention than in the case of the conventional implants. On the other hand, the pores are smaller in the case of the conventional implants.

Claims

1. Flexible implant, with a mesh-like basic structure
    of monofilaments, the diameter of which is in the
    range from 0.02 mm to 0.30 mm and the bending elas-
    ticity modulus of which is smaller than 3500 N/mm^2,
    the basic structure containing pores the size of
    which lies in the range from 1.5 mm to 8.0 mm over
    more than 90% of the total area of the pores, and
    the bending force of the basic structure, measured
    in a three-point bending test with a span of 11 mm
    and normalized to a sample width of 10 mm, being 30
    mN at most.

2. Implant according to claim 1, characterized in that
    the basic structure contains monofilaments of at
    least one of the following materials: thermoplasti-
    cally workable fluorinated homopolymers, thermoplas-
    tically workable fluorinated copolymers, polyole-
    fins, mixtures of the aforementioned materials.

3. Implant according to claim 2, characterized in that
    the basic structure contains monofilaments of at
    least one of the following materials: polyvinylidene
    fluoride, copolymers of vinylidene fluoride and
    hexafluoropropene, mixtures of the aforementioned
    materials.

4. Implant according to claim 3, characterized in that
    the basic structure contains monofilaments of at
    least one of the following materials: mixtures of
    polyvinylidene fluoride and a copolymer of 95 wt.-%
    vinylidene fluoride and 5 wt.-% hexafluoropropene,
    preferably in the mixture ratio 50/50 or 80/20.

5. Implant according to one of claims 1 to 4, characterized in that the basic structure contains monofilaments of a resorbable material.

6. Implant according to claim 5, characterized in that the basic structure contains monofilaments of at least one of the following materials: poly-p-dioxanone, copolymers of glycolides and caprolactones.

7. Implant according to one of claims 1 to 6, characterized in that the tensile strength of at least part of the monofilaments is at least 400 N/mm^2.

8. Implant according to one of claims 1 to 7, characterized in that the basic structure contains a weft-knitted product or a warp-knitted product, preferably a warp-knitted product made as crochet galloon ware.
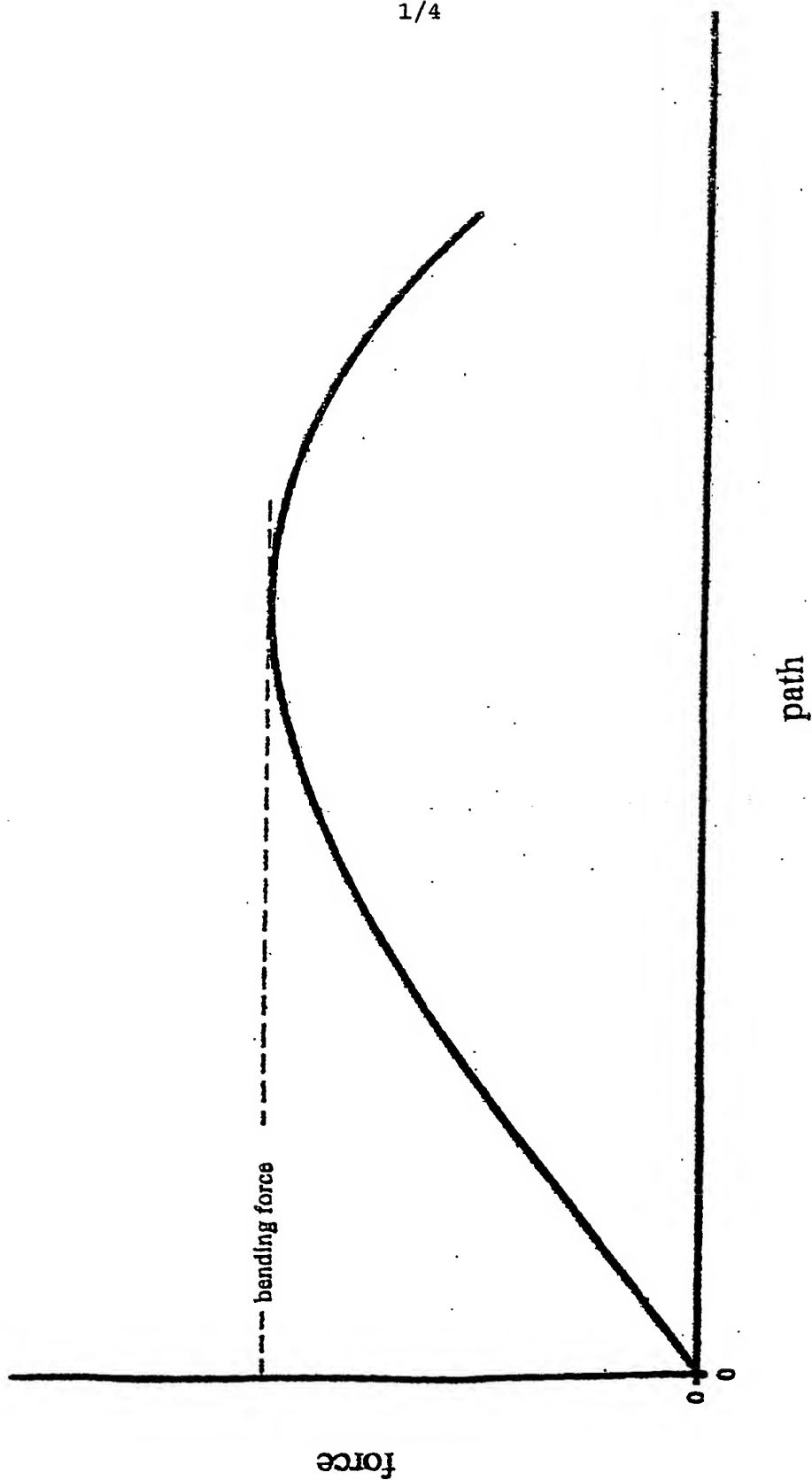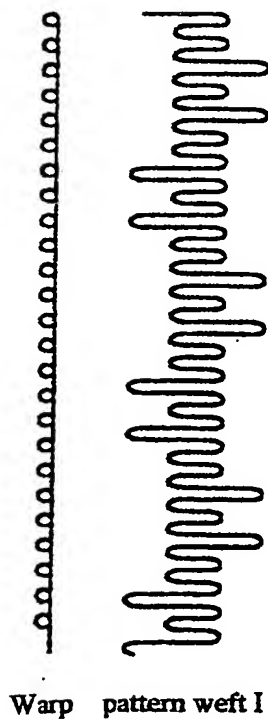
Fig. 1

Machine type: Raschelina RD3MT3/420SN
Machine gauge: 8 needles/cm
Stitch density: 15.0 stitches/cm   (meshes/cm)
Repeat value: 18 stitches/repeat

Warp: closed fringe   (closed pillar stitch)
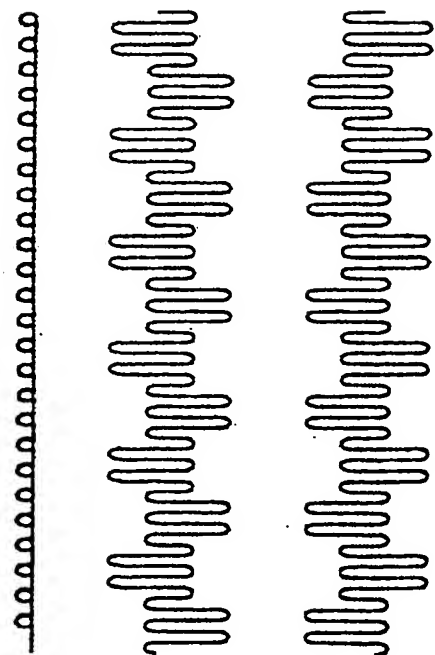Bar 3: pattern weft I

Pattern template	
Warp	Bar 3
0	6
2	2
	4
	2
	6
	2
	4
	2
	4
	0
	4
	2
	4
	0
	4
	2
	4
	2

Warp   pattern weft I

Fig. 2

3/4

Machine type:	Raschelina RD3MT3/420SN
Machine gauge:	8 needles/cm
Stitch density:	15.5 stitches/cm (meshes/cm)
Repeat value:	10 stitches/repeat

Warp: closed fringe   (closed pillar stitch)
Bar 3: pattern weft I
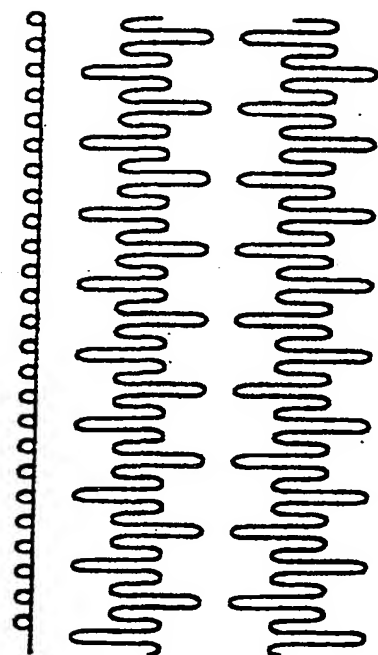Bar 4: pattern weft II

Pattern template		
Warp	Bar 3	Bar 4
0	6	2
2	2	6
	6	2
	2	6
	6	2
	4	4
	8	0
	4	4
	8	0
	4	4

Warp   pattern weft I pattern weft II

Fig. 3

4/4

Machine type: Raschelina RD3MT3/420SN
Machine gauge: 8 needles/cm
Stitch density: 16.9 stitches/cm   (meshes/cm)
Repeat value: 6 stitches/repeat

Warp: closed fringe   (closed pillar stitch)
Bar 3: pattern weft II
Bar 4: pattern weft I

| Pattern template | | |
Warp	Bar 3	Bar 4
0	4	4
2	0	8
	4	4
	2	6
	6	2
	2	6

Warp   pattern weft I pattern weft II

Fig. 4